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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,897	09/05/2003	Joel W. Schwartz	VBLT:014US	1548
32425	7590	10/30/2006		
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/656,897

Applicant(s)

SCHWARTZ ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 20, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-19, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement, filed 15 December 2003, has been entered into the record. Applicants' election without traverse of Group I (Claims 1-19, 21 and 22), in the Paper of 30 June 2006, is acknowledged. Claims 20, 23 and 24 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-19, 21 and 22 are under examination in the instant application.

### **Claim Rejections/Objections**

#### **Claim Objections**

Claim 13 is objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

#### **Claim Rejections- 35 USC § 112, first paragraph - scope of enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-12, 14-19, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using 4-(4-dimethylaminostyryl)-N-

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methyl- pyridinium ( $ASP^+$ ) to measure transporter activity of the norepinephrine transporter, *NET*, does not reasonably provide enablement wherein  $ASP^+$  is used to measure the activity of other neurotransmitter transporters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-12, 14-19, 21 and 22 are drawn to methods of measuring the activity of a transporter as well as using the transporter to screen for agents that modulate the transporter. The specification discloses using  $ASP^+$  to test noradrenergic transporters in the same way that  $MPP^+$  has been used to study the kinetics of dopaminergic transporters (Brandis, K., 2006, *Eukaryon*, 2: 22-27), but without causing the cell death that is a consequence of using  $MPP^+$ . The scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The specification discloses experiments in which the activity of *NET* was measured in the presence of the artificial substrates  $APP^+$  and  $MPP^+$  in several transfected cells and in one cell line that expresses *NET* endogenously (see Figure 1). Experiments were also described in which it was shown that  $ASP^+$  competes with norepinephrine (NE) transport. Additional studies showed that  $ASP^+$  accumulation is sensitive to cocaine and desipramine.

The specification as well as the inventors' own published research (Schwartz, et al, 2003, *J. Biol. Chem.* 278 (11): 9768-9777) cite evidence that  $ASP^+$  can be used to study noradrenergic (NET) transporters. However, there is no evidence that the artificial substrate  $ASP^+$  can also be used to examine the kinetics of other transporters, even neurotransmitter transporters.

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Transporters are rather specific for their substrates (Peter, et al, 1996, J. Biol. Chem., 271(6): 2979-2986) and the Specification does not demonstrate that *NET*'s interaction with ASP<sup>+</sup> has the same specificity and kinetics as is typical of other neurotransmitter transporters.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Due to the large quantity of experimentation required to determine how to use ASP<sup>+</sup> in conjunction with transporters other than *NET* in measuring neurotransmitter transport, the lack of direction or guidance in the specification regarding same (e.g., the lack of guidance regarding transporter experiments using ASP<sup>+</sup> and other transporters), the lack of working examples that read on use of other transporters, the state of the art showing that neurotransmitter transporters differ in their substrate specificities, and the breadth of the claims which embrace several unrelated transporters - undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

**Conclusion:** Claims 1-12, 14-19, 21 and 22 are not allowable for the reasons cited above.

Claim 13 is objected to.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the


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examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW  
19 October 2006

  
EILEEN B. O'HARA  
PRIMARY EXAMINER